UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,125	04/08/2004	Mike Favet	GUID.119PA	8214

51294 7590 11/06/2006

HOLLINGSWORTH & FUNK, LLC
8009 34TH AVE S.
SUITE 125
MINNEAPOLIS, MN 55425

EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,125	FAVET ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) *16-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I (claims 1-15) in the reply filed on 23 October 2006 is acknowledged. The traversal is on the ground(s) that "the Examiner does not explain or provide support in her conclusion that the subject matter of each respective invention has been recognized as having acquired separate status in the art." The applicant argues that "all of the inventions are group together in class 607, subclass 4," and that "Inventions I, II, and II are all directed to treating asystole." These arguments are not found persuasive because the groups of claims comprise divergent subject matter, regardless of their placement in the art. As claimed, group I applies to delivery of pacing therapy in response to detection of cardiac asystole only (lines 14-15 of the claim), whereas claim 16 applies to delivery of pacing therapy in response to any cardiac condition, which includes arrhythmias or fibrillation. Further, as to the distinction between groups I and III, the applicant argues that "the addition of a lead does not present 'a serious burden' when searching the prior art." The examiner respectfully disagrees. As previously mentioned, these claims pertain to different subject matter (i.e., leaded versus leadless systems) and are therefore different inventions.

2. The requirement is still deemed proper and is therefore made FINAL. Claims 16-67 are withdrawn, and claims 1-15 are pending.

Claim Objections

3. Claims 16-67 are objected to because of the following informalities: the status indicators show these claims as "Original" rather than "Withdrawn" or "Cancelled" as would be appropriate for a nonelected group of claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill (U.S. 5,074,301). Regarding claims 1-6 and 11, Gill discloses (col. 3, lines 49-52; Figure 1) a system (1) "designed to be implantable in a patient and includes a pulse module (10) and appropriate leads fro connecting module to a patient's heart (11)." The examiner considers this to be a housing configured for implantation in a patient and a lead system comprising one or more lead electrodes. A pacemaker is provided (col. 4, lines 22-55; Figure 2) that comprises "circuitry for atrial pacing (24), ventricular pacing (34), atrial sensing (25), ventricular sensing (35) and telemetry (30). In addition, pacemaker (17) includes a control block (39) which includes an interface to microprocessor (19)." The examiner considers this to be energy delivery circuitry provided in the housing, detection circuitry and control circuitry coupled to the energy

delivery circuitry and the detection circuitry. Gill further discloses (col. 6, lines 1-16; Figure 4B) an ECG trace outlining a "defibrillation shock sequence in which the defibrillation shock therapy is preceded by a pre-shock atrial pace. At (80), a VT/VF [ventricular fibrillation or ventricular tachycardia] arrhythmia has developed. Prior to the delivery of defibrillation shock therapy at (82), a pacing pulse is delivered to the atrium at (81). The timing of the pacing pulse is such that it renders the atrium depolarized during the subsequent delivery of the shock." As shown at (83), "the defibrillation shock has succeeded in reverting the VT/VF arrhythmia and normal sinus rhythm is present." The examiner considers this to be an energy delivery circuitry that is capable of delivering a therapy to treat a tachyarrhythmia, in response to detection of a tachyarrhythmia requiring treatment. A defibrillation shock (col. 6, lines 34-44; Figure 4C) "which has succeeded in reverting the VT/VF arrhythmia, is followed by a post-shock delay, as shown at (93). At (94), asystole is detected and thus bradycardia pacing is commenced, about 4 seconds after the delivery of the defibrillation shock. By this time, the pro-arrhythmic effect of a premature recommencement of bradycardia support pacing immediately post reversion has been avoided, as there has been sufficient time for the patient's heart's conduction system to become reorganized and susceptible to bradycardia support pacing." The examiner considers this to be energy delivery circuitry that is capable of delivering a non-physiological, life sustaining pacing therapy in response to detection of cardiac asystole.

6. Regarding claims 7-10 and 12, Gill discloses, (col. 1, lines 22-32) "The term therapy as used herein includes the processes used between the detection and the

reversion of a tachyarrhythmia and includes the actions of antitachycardia pacing, cardioversion and/or defibrillation shocks. The term cardioversion refers to the discharge of electrical energy into the cardiac tissue in an attempt to terminate or revert a tachyarrhythmia. This may take the form of a high energy discharge (up to 40 Joules or more) or a low energy discharge (less than 1 Joule). The discharge may be monophasic or biphasic but is not restricted to these waveforms." The examiner considers this to teach a tachyarrhythmia therapy that includes anti-tachycardia pacing therapy, treatment of cardiac fibrillation and bi- or monophasic defibrillation therapy.

7. Further regarding claim 12, Gill discloses, (col. 4, lines 1-5) "Defibrillator (16) produces a high voltage to charge its capacitors and then discharges them in response to control signals from microprocessor. A defibrillator electrode lead (14) transfers the energy of a defibrillator shock (15) from the implanted pulse module (10) to the surface of the heart (11)." The examiner considers this to be an energy delivery circuit that comprises a capacitor circuit; a tachyarrhythmia therapy that comprises a defibrillation therapy and a cardioversion therapy that is delivered prior to or during charging of a capacitor of the capacitor circuit.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (U.S. 5,074,301). Gill discloses the claimed invention but does not disclose expressly the electrodes being intrathoracic, subcutaneous or on the housing of the implantable device. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the endocardial electrodes as taught by Gill, with the electrode arrangements as claimed, because the applicant has not disclosed the electrode arrangements provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead electrodes as taught by Gill, because they are able to effectively sense and pace the heart, as claimed. Furthermore, it is well known in the art to use intrathoracic, subcutaneous or can electrodes for the claimed purposes. Therefore, it would have been an obvious matter of design choice to modify the electrode placement to obtain the invention as specified in the claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Deborah L. Malamud
Patent Examiner
Art Unit 3766